



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Application: Catalent CTS, LLC

[Docket No. DEA-696]

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Catalent, CTS LLC applied to be registered as an importer of the following basic class(es) of controlled substances: Gamma Hydroxybutyric Acid, Marihuana Extract, Marihuana, and Tetrahydrocannabinols.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 17, 2020, Catalent, CTS LLC, 10245 Hickman Mills Drive, Kansas City, Missouri 64137, applied to be registered as an importer of the following basic class(es) of controlled substances:

| Controlled Substance | Drug Code | Schedule |
|---------------------------|-----------|----------|
| Gamma Hydroxybutyric Acid | 2010 | I |
| Marihuana Extract | 7350 | I |
| Marihuana | 7360 | I |
| Tetrahydrocannabinols | 7370 | I |

The company plans to import finished dosage unit products containing Gamma-Hydroxybutyric Acid and Marihuana Extracts for clinical trial studies. These Marihuana Extracts compounds are listed under drug code 7350. No other activity for these drug codes is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,
Assistant Administrator.

